**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

KANEKA CORPORATION,
A Japanese Corporation.

Plaintiff,

v.

DESIGNS FOR HEALTH, INC., A Delaware Corporation, and AMERICAN RIVER NUTRITION, LLC, A Delaware Corporation.

Defendants.

**C. A. No. 21-00209 (RGA)**

**PUBLIC VERSION**

**DEFENDANTS' BRIEF IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT AND MOTIONS TO EXCLUDE OPINIONS OF PLAINTIFF'S EXPERTS**

# TABLE OF CONTENTS

**Page(s)**

# TABLE OF AUTHORITIES

**Page(s)**

**CASES**

**STATUTES**



**OTHER AUTHORITIES**

## I. INTRODUCTION

Defendants Designs for Health, Inc. ("DFH") and American River Nutrition, LLC ("ARN") (collectively, "Defendants") move this Court for summary judgment on Plaintiff Kaneka Corporation's ("Kaneka") claims. Summary judgment is appropriate because the asserted claims of United States Patent No. 7,145,044 ("the '044 Patent") and United States Patent No. 7,829,080 ("the '080 Patent") (collectively, "the Patents-in-Suit") are invalid under 35 U.S.C. §§ 101, 102, 103, and 112. Further, summary judgment should be granted on the claim for lost profits as a matter of law. Defendants also move this Court to exclude the expert testimony of Kaneka's technical expert, Dr. Allan S. Myerson ("Dr. Myerson") and Kaneka's damages expert, Sam Rosenfarb ("Rosenfarb").

## II. SUMMARY OF THE ARGUMENTS

1. The Patents-in-Suit are invalid under 35 U.S.C. § 101 because they are directed to a natural product and/or natural phenomenon—reduced Coenzyme $Q_{10}$—and the claims of the Patents-in-Suit do not contain an eligible inventive concept.

2. The Patents-in-Suit are invalid under 35 U.S.C. § 102 because the prior art discloses claims 1 and 13 of the '044 Patent and claims 5 and 15 of the '080 Patent.

3. The Patents-in-Suit are invalid under 35 U.S.C. § 103 for obviousness because they merely combine elements and features that were known in the prior art in a known, and predictable way.

4. The '080 Patent lacks enablement and a sufficient written description to satisfy 35 U.S.C. § 112. Additionally, claims 5 and claims 15 of the '080 Patent are indefinite.

5. Defendants request that the Court exclude opinions of Kaneka's technical expert, Dr. Allan S. Myerson, because his opinions are unreliable under *Daubert* and Fed. R. Evid. 702.

Specifically, he (1) relies on an improper legal standard and improper claim construction of "hydrocarbon" in forming his opinions; (2) bases his opinions on improper sample preparation and analysis; and (3) reaches inconsistent conclusions between his expert report and reply report.

6. Defendants request that the opinions of Kaneka's damages expert, Sam Rosenfarb, be excluded because Mr. Rosenfarb's opinions on lost profits are unreliable under *Daubert* and Fed. R. Evid. 702.

## III. BACKGROUND

### A. Coenzyme $Q_{10}$

Coenzyme $Q_{10}$ ("$CoQ_{10}$") is a natural compound found in human, animal, and plant tissues. $CoQ_{10}$ is found naturally in both its oxidized form (ubiquinone) and reduced form (ubiquinol). (*See* Declaration of Richard F. Taylor, Ph.D. ("Taylor Decl."), ¶ 37, Ex. 8 at 232-233). Ubiquinol and Ubiquinone are chemically identical, except that the reduced form of a molecule of ubiquinol contains two more electrons than a molecule of ubiquinone. (*See* Taylor Decl., ¶ 62, Ex. 15 at 8). Ubiquinone derives its name from the word "ubiquitous" because it is present everywhere in the human body, as part of cells' mitochondria. (*See Id.*, ¶ 85, Ex. 9 at 308-314). $CoQ_{10}$ primarily aids in energy conservation and, because of this function, exists in numerous organs, including the heart, kidneys, liver, muscles, pancreas, and thyroid. Ubiquinol is the form that is most readily available for use in the body.

$CoQ_{10}$ is especially important for generating energy (via adenosine triphosphate) in the mitochondria inside most cells. For this reason, $CoQ_{10}$ is especially abundant in tissues with high energy demands such as the pancreas, intestines, brain, lungs, heart and liver. Reduced $CoQ_{10}$ is regularly taken as a dietary supplement to improve energy levels.

Kaneka itself has explained the natural sources and natural phenomena related to Coenzyme Q compounds in submissions made to the Food and Drug Administration to market its ubiquinol products. (*See* Taylor Decl., ¶ 62, Ex. 15 at 8-9). In that submission, of which the Court may take judicial notice under Fed. R. Evid. 201, Kaneka unequivocally stated that Coenzyme $Q_9$ and Coenzyme $Q_{10}$ are naturally occurring substances that occur in many plants and animals:

> Ubiquinol is the two-electron reduction product of coenzyme $Q_{10}$ ($CoQ_{10}$), a naturally-occurring, lipid-soluble nutrient (Frei *et al.*, 1990; Schoepp, 1997; Pepping, 1999). The term CoQ refers to a class of homologous benzoquinones that have been identified in all plants and animals, as well as in a majority of microorganisms (Budavari *et al.*, 1996; Nohl *et al.*, 1998). Benzoquinone homologs consist of a redox active quinoid moiety, and a hydrophobic side chain comprised of 6 to 10 isoprenoid units, depending on the species (Ibrahim *et al.*, 2000; Matthews *et al.*, 1998; Lenaz, 2001). In humans and most mammals, including dogs, the predominant form of coenzyme Q is coenzyme $Q_{10}$ ($CoQ_{10}$), which consists of 10 isoprenoid units in the side chain (Ramasarma, 1985). In rats and mice the primary form is coenzyme $Q_9$, which contains 9 isoprenoid units, however, low levels of coenzyme $Q_{10}$ have also been reported (Battino *et al.*, 1992). Coenzyme $Q_{10}$ and its reduced form are also referred to as ubiquinone (ubiquinone-10) and ubiquinol (ubiquinol-10), respectively.

(*Id.* at 8 (emphasis added)). Kaneka further represented to FDA that:

> Although coenzyme $Q_{10}$ becomes oxidized as a result of its antioxidant function, a substantial amount is maintained in its reduced state in the plasma membrane and endomembranes (Takahashi et al., 1993), as well as in lipoproteins (Stocker and Frei, 1991). In the plasma membrane, reduction of coenzyme $Q_{10}$ is achieved through the involvement of several CoQ reductases (e.g., DT-diaphorase and NADPH-CoQ reductase) that may be either integral membrane proteins or cytosolic enzymes (Arroyo et al., 2000). Stocker and Suarna (1993) also reported that natural ubiquinones are readily reduced after dietary uptake. While it is generally accepted that oxidized coenzyme $Q_{10}$ is the final product of its biosynthetic pathway, some authors (Stocker and Suarna, 1993; Schultz et al., 1996) have proposed that the de novo synthesis of the hydroquinone also contributes, at least in part, to the high levels of ubiquinol observed in vivo. In fact, ubiquinol is the most common form of coenzyme $Q_{10}$ in vivo (Frei et al., 1990), and represents more than 80% of the total ubiquinol-10 + coenzyme $Q_{10}$ pool in human plasma, intestine and liver (Edlund, 1988; Okamoto et al., 1989; Åberg et al., 1992). In the plasma of healthy adults, ubiquinol-10 accounts for approximately 95% of the total concentration, while ubiquinone-10 accounts for only 5% (Yamashita and Yamamoto, 1997); in human urine, ubiquinol-10 accounts for approximately 59% of the total ubiquinone-10 concentration (Okamoto et al.,

> 1989). Åberg et al. (1992) reported that high levels of reduction (70 to 100%) were also observed in human tissues including, the liver, pancreas, and intestine. Only in the brain and lung was most of the ubiquinone (approximately 80%) in the oxidized state. In contrast, the degree of ubiquinone reduction in all rat tissues was less than in corresponding human tissues.

(*Id*. at 9 (emphasis added)).

**B. The Parties**

ARN manufactures and produces ingredients for nutritional supplements, including DuoQuinol, which is a formulation containing ubiquinol. (D.I. 75 ¶ 2). DFH distributes and sells nutritional supplements containing DuoQuinol®, including its products CoQnol™ and Q10.1™. (*Id.* ¶ 17). Kaneka alleges that the DuoQuinol, CoQnol, and Q10.1 products infringe on the ’044 Patent and the ’080 Patent. (*Id.*)

**C. The ’044 Patent**

The ’044 Patent purportedly discloses a “[m]ethod of producing reduced coenzyme $Q_{10}$ using solvent with high oxidation-protective effect.” (’044 Patent at Cover (54)). Kaneka has asserted Claims 1 and 13 of the ’044 Patent against Defendants. (D.I. 75 ¶ 29). Claim 1 of the ’044 Patent provides: “A method of crystallizing reduced coenzyme $Q_{10}$, which comprises crystallizing the reduced coenzyme $Q_{10}$ using, as a solvent, at least one species selected from the group consisting of hydrocarbons, fatty acids esters, ethers and nitriles.” (’044 Patent at Col. 21, ll. 16-20). Claim 13 of the ’044 Patent provides: “A reduced coenzyme $Q_{10}$ crystal with a reduced coenzyme $Q_{10}$/oxidized coenzyme $Q_{10}$ weight ratio of not lower than 96/4.” (*Id.* at Col. 21, ll. 59-61). The ‘044 Patent expired on September 12, 2022.

**D. The ’080 Patent**

The ’080 Patent purportedly discloses a “[s]tabalization method of reduced coenzyme $Q_{10}$.” (’080 Patent at Cover (54)). Kaneka has asserted Claims 5 and 15 of the ’080 Patent against the defendants. (D.I. 75 ¶ 37.) Claim 5 of the ’080 Patent provides:

> A reduced coenzyme $Q_{10}$-containing composition comprising reduced coenzyme $Q_{10}$ and one or both (a) and (b):
>
> (a) not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme $Q_9$ relative to reduced coenzyme $Q_{10}$ and
>
> (b) reduced coenzyme $Q_{11}$
>
> wherein not less than 0.01 wt % of reduced coenzyme $Q_{10}$ is contained in the composition, and wherein the proportion of reduced coenzyme $Q_{10}$ relative to the total amount of coenzyme $Q_{10}$ is not less than 90 wt %.

('080 Patent at Col. 16, ll. 55-65). Claim 5 of the '080 Patent recites that the claim can contain "**one or** both of (a) and (b)," (emphasis added) wherein "(a)" refers to the potential inclusion of Coenzyme $Q_9$ ("$CoQ_9$") whereas "(b)" refers to the potential inclusion Coenzyme $Q_{11}$ ("$CoQ_{11}$"). (Taylor Decl., ¶ 78). Because the claimed composition may include one or both, this means that the claim need not be interpreted to include all three homologs (i.e., the three identified forms of Coenzyme Q: $CoQ_9$, $CoQ_{10}$, and/or $CoQ_{11}$). (*Id.*) As such, prior art or natural compositions containing element (a) or element (b), i.e., $CoQ_{10}$ and $CoQ_9$ **or** $CoQ_{10}$ and $CoQ_{11}$, along with the other elements of the claims, would render the claim invalid. (*Id.*)

Aside from reciting generic method steps, claim 15 of the '080 Patent is nearly identical to claim 5, and the recited composition is the same. Claim 15 recites:

> A method for producing a reduced coenzyme $Q_{10}$-containing composition, which method comprises
>
> providing a composition comprising oxidized coenzyme $Q_{10}$ with one or both of oxidized coenzyme $Q_9$ and oxidized coenzyme $Q_{11}$, and then
>
> reducing oxidized coenzyme $Q_{10}$ and reducing one or both of oxidized coenzyme $Q_9$ and oxidized coenzyme $Q_{11}$ to prepare the reduced coenzyme $Q_{10}$-containing composition,
>
> wherein the composition comprises reduced coenzyme $Q_{10}$ and one or both of (a) not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme $Q_9$ relative to reduced coenzyme $Q_{10}$ and (b) reduced coenzyme $Q_{11}$,
>
> wherein not less than 0.01 wt % of reduced coenzyme $Q_{10}$ is contained in the composition, and
>
> wherein the proportion of reduced coenzyme $Q_{10}$ relative to the total amount of coenzyme $Q_{10}$ is not less than 90 wt %.

('080 Patent at Col. 18, ll. 4-21.).

### E. Nature and Stage of Proceedings

Kaneka filed the original complaint on February 16, 2021. (D.I. 1) asserting infringement of two patents—the ’044 Patent and the ’080 Patent (collectively, the “Patents-in-Suit”). Kaneka filed the Second Amended Complaint on July 8, 2022, which alleges that Defendants’ DuoQuinol, CoQnol, and Q10.1 products (the “Accused Products”) infringed claims 1 and 13 of the ’044 Patent and claims 5 and 15 of the ’080 Patent (“the Asserted Claims”).[1] (D.I. 75 ¶¶ 29, 37.) Kaneka alleges three counts against Defendants: (1) direct infringement of the ’044 Patent against DFH; (2) direct infringement of the ’080 Patent against DFH; and (3) induced infringement of the ’044 Patent and the ’080 Patent against ARN. (D.I. 75 ¶¶ 28-48). On July 22, 2022, Defendants denied the material allegations of the amended pleading and asserted four counterclaims against Kaneka: (1) declaration of non-infringement of the ’044 Patent; (2) declaration of non-infringement of the ’080 Patent; (3) declaration of invalidity of the ’044 Patent; and (4) declaration of invalidity of the ’080 Patent. (D.I. 79 at 10-11.)

The parties agreed to construe each claim term using its plain and ordinary meaning. (D.I. 55.) Fact discovery closed on June 21, 2022, and expert discovery closed on December 28, 2022. (D. I. 105). Trial is scheduled for April 17, 2023. (D.I. 19 at 10.)

## IV. DEFENDANTS ARE ENTITLED TO SUMMARY JUDGMENT BECAUSE THE PATENTS-IN-SUIT ARE INVALID

### A. Legal Standard

Summary judgment is appropriate where “the movant shows there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). The “mere existence of a scintilla of evidence” cannot defeat a motion for summary

[1] Kaneka’s Second Amended Complaint dropped the allegation that Defendants infringed claim 1 of the ’080 Patent. Kaneka added an additional product to the Accused Products in its Second Amended Complaint—that is, Q10.1.

judgment; there must be "evidence on which the jury could reasonably find" for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986). Patent eligibility can be decided on summary judgment. *Ficep Corp. v. Peddinghaus Corp.*, 587 F. Supp. 3d 115, 120 (D. Del. 2022) (quoting *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1128 (Fed. Cir. 2018)).

**B. The Patents-in-Suit are Invalid Under 35 U.S.C. § 101.**

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. However, courts have recognized that § 101 "contains an important implicit exception. '[L]aws of nature, natural phenomena, and abstract ideas' are not patentable." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012) (alteration in original) (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)). "Whether a claim is drawn to patent-eligible subject matter under 35 U.S.C. § 101 is a threshold inquiry to be determined as a matter of law in establishing the validity of a patent." *Cloud Satchel, LLC v. Amazon.com, Inc.*, 76 F. Supp. 3d 553, 558 (D. Del. 2014) (citing *CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1277 (Fed. Cir. 2013), aff'd, *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014)).

In determining whether a patent is invalid under § 101, courts apply the two-step framework set forth in *Mayo Collaborative Servs. v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), and applied in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217-18 (2014). First, a court determines whether the claims at issue are "directed to" a patent-ineligible concept, such as a natural phenomenon. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 749 (Fed. Cir. 2019) (quoting *Alice Corp*, 573 U.S. at 217).

If a patent claim is found to be directed to a natural product or natural phenomenon, the second inquiry asks "whether the limitations of the claim apart from the law of nature, considered individually and as an ordered combination, transform the nature of the claim into a patent-eligible concept." *Athena Diagnostics, Inc., LLC,* 915 F.3d at 749 (cleaned up). "[W]ell-understood, routine, conventional activity already engaged in by the scientific community" is insufficient to transform a patent-ineligible concept into a patentable invention. *Mayo*, 566 U.S. at 79-80. Indeed, "a claim may be held ineligible if it invokes a natural law to achieve some desired result without reciting any further limitations as to the means for accomplishing that result." *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 966 F.3d 1347, 1352 (Fed. Cir. 2020). Courts can, and often do, look to the specification of the patent itself to determine whether any claim elements are directed to merely well-understood, routine, and conventional activity already engaged in by the scientific community. *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1355 (Fed. Cir. 2016) (finding claims invalid under § 101 where "[n]othing in the claims, understood in light of the specification, requires anything other than off-the-shelf, conventional" components.); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1362 (Fed. Cir. 2017) (finding patents were "directed to patent-ineligible subject matter" because the patents' specifications described the techniques as well-understood and conventional and because "transforming claims that are directed to a law of nature requires more than simply stating the law of nature while adding the words 'apply it'").

Here, as explained further below, the Asserted Claims are directed toward natural products or natural phenomena, and the claims do not disclose "inventive concept[s]" that transforms the claims into a patent-eligible application thereof. *See Alice*, 573 U.S. at 217-18. Specifically, the steps utilized in the '044 Patent and '080 Patent were conventional, routine, or well-understood at

the time of the invention. (*See* '044 Patent at Col. 12, ll. 44-47;'044 Patent at Col. 13, ll. 23-27; '080 Patent at Col. 5, ll. 48-54). To the extent that the Asserted Claims contain any aspect that differs from the natural product or natural phenomena recited in the claims, it not markedly different from that which occurs naturally or fails to set forth the means for accomplishing the desired result in an inventive manner. Accordingly, the asserted claims of the Patents-in-Suit are invalid for failure to satisfy the requirements of 35 U.S.C. § 101.[2]

**1. Claims 5 and 15 of the '080 Patent are invalid under 35 U.S.C. § 101 because they do not recite patent-eligible subject matter.**

Claims 5 and 15 of the '080 Patent both recite a composition containing a combination of naturally occurring Coenzyme Q homologs listed in relative amounts. (Taylor Decl., ¶ 43, Ex. 3 at ¶¶ 48-52, Ex. 5 at ¶ 18, Ex. 8 at 232-233). Claims 5 and 15 of the '080 Patent differ only in that claim 15 is a generically recited method claim that results in the composition claimed in claim 5. (Taylor Decl., ¶ 35, Ex. 3 at ¶¶ 30-32, 45). Generic, unspecified steps such as "producing," "providing," and "reducing" do not confer any specific activity that would be undertaken to produce the resulting composition. Such results-based, method steps that lack any specificity or inventiveness should be given little, if any, patentable weight. *See, e.g.*, *Nabors Drilling Techs. USA Inc. v. Helmerich & Payne Int'l Drilling Co.*, No. 3:20-CV-03126-M, 2022 WL 4589093, at *3 (N.D. Tex. Sept. 28, 2022) (collecting cases); *see also See Genetic Veterinary Sci., Inc. v.*

[2] The Patents-in-Suit issued prior to the Supreme Court's decisions in *Mayo* and *Alice*, and their § 101 validity has never been considered by the United States Patent and Trademark Office under those decisions' framework. (*See* '044 Patent at Cover (45); '080 Patent at Cover (45)). When assessed under the rubric of *Mayo* and *Alice*, it is evident that the Asserted Claims of the Patents-in-Suit are directed to a method of forming a naturally occurring compound—reduced $CoQ_{10}$—and the elements recited are expressly described in the patents as conventional and routine. *See CertusView Tech., LLC v. S & N Locating Servs, LLC*, 287 F. Supp. 3d 580, 594 (E.D. Va. 2018) (noting that only claims issued after *Mayo* were "entitled to a presumption of validity under the current legal standard for patent eligibility"); *see also Inventor Holdings, LLC v. Bed Bath & Beyond, Inc.*, 876 F.3d 1372, 1379 (Fed. Cir. 2017) (It is the patentee's "responsibility to reassess its case in view of new controlling law.").

*LABOKLIN GmbH & Co. KG*, 933 F.3d 1302, 1317 (Fed. Cir. 2019) (finding asserted claims were not directed to a new and useful method because the claims begin and end with a naturally occurring phenomenon); *Mayo*, 132 S.Ct. at 1300 ("[S]imply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable."). Claims directed to laws of nature are ineligible for patent protection when, "(apart from the natural laws themselves) [they] involve well-understood, routine, conventional activity previously engaged in by researchers in the field." *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1376 (Fed. Cir. 2016) (quoting *Mayo*, 566 U.S. at 74). Here, the method of claim 15 begins and ends with the composition recited in claim 5. Accordingly, the analysis of these claims is very similar given that there is no inventive distinction between the method of claim 15 and the composition of claim 5 of the '080 Patent.

**a. Claim 5 of the '080 Patent is directed toward a natural composition because it is not markedly different from that which exists in nature.**

Claim 5 is directed toward a natural composition because is directed toward a composition containing various amounts (or, in some instances, none) of reduced $CoQ_{10}$, oxidized $CoQ_{10}$, reduced $CoQ_9$, and reduced $CoQ_{11}$. (*See* Taylor Decl., ¶ 36, Ex. 3 at ¶ 28). The parties do not dispute that $CoQ_{10}$ and $CoQ_9$ exist naturally in combination in both their oxidized and reduced forms in human tissues, along with rat tissues. (Taylor Decl., ¶ 37, Ex. 3 at ¶ 47, Ex. 8 at 232-233; Ex. 15). Claim 5 does nothing to transform the underlying natural products into a non-natural composition because it does no more than recite a combination of naturally occurring elements. Patent claims directed to compositions lacking "markedly different characteristics from any found in nature" are ineligible under § 101. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 590–91 (2013) (explaining that the natural bacterial mixture of *Funk Brothers Seed Co. v. Kalo Inoculant*, 333 U.S. 127 (1948) "was not patent eligible because the patent holder did not

alter the bacteria in any way."); *see also In re Bhagat*, 726 F. Appx. 772, 779 (Fed. Cir. 2018) ("Applicant has not shown that the claimed mixtures are a 'transformation' of the natural products, or that the claimed mixtures have properties not possessed by these products in nature."). As routinely held by the courts, merely mixing natural components into a natural composition is insufficient to elevate those from that which exists in nature. *See id*. Therefore, Kaneka's mere combination of certain quantities of natural Coenzyme Q homologs in the proportions recited by claim 5 of the '080 Patent are not markedly different than that which exists naturally.

**b. When considered as a whole, claim 5 of the '080 Patent lacks an inventive concept because the claim combines natural compounds using well-known, routine, and conventional methods.**

The '080 Patent admits that the compositions recited in the claims can be made using "any suitable technique," such as those prior art methods described in the '044 Patent:

> In the stabilization method of the present invention, the aforementioned (a) and/or (b) can be separately prepared by any suitable technique. For example, the separate preparation can be preparation by extraction and purification from a naturally occurring substance, reduction of oxidized coenzyme $Q_9$ and oxidized coenzyme $Q_{11}$ according to the aforementioned method described in WO 03/06408, or coupling reaction of isoprenyl side chain with 2-methyl-5,6-dimethoxy-1,4-benzohydroquinone and the like. The reduced coenzyme $Q_{10}$ can also be stabilized by adding (a) and/or (b) obtained by such preparation to reduced coenzyme $Q_{10}$.
>
> The stabilization method of the present invention also includes the co-presence of reduced coenzyme $Q_{10}$ and (a) and/or (b) by the reduction of oxidized coenzyme $Q_{10}$ containing oxidized coenzyme $Q_9$ and/or oxidized coenzyme $Q_{11}$.
>
> The method of reducing oxidized coenzyme $Q_{10}$ containing oxidized coenzyme $Q_9$ and/or oxidized coenzyme $Q_{11}$ can be performed according to the method described in WO 03/06408 and the like.

('080 Patent at Col. 5, ll. 47-63 (emphasis added)).[3] Consequently, the '080 Patent's disclosure instructs that the composition of claim 5 is made using nothing more than routine, conventional,

[3] While the '080 Patent cites directly to International Publication No. WO 03/06408, the Court should take official notice that publication corresponds with the U.S.-filed patent application that issued as the '044 Patent. ('044 Patent, Cover at (87)).

and well-understood techniques.

Moreover, the prior art evidences that $CoQ_{10}$ and $CoQ_9$ exist naturally in combination in both their oxidized and reduced forms. (Taylor Decl., ¶ 37, Ex. 3 at ¶ 47, Ex. 8 at 232-233). For example, the Aberg reference discusses naturally occurring reduced Ubiquinone-9 and Ubiquinone-10 in rat and human tissues.[4] (Taylor Decl., ¶ 84, Ex. 3 at ¶ 47, Ex. 8 at 232-233). Aberg explains that Ubiquinone-9 and Ubiquinone-10 are primarily present in their reduced forms, and entirely in their reduced forms in certain tissues, such as human liver, pancreas, and intestine. (*Id.*) Thus, although Aberg generically refers to the Coenzyme Q compounds as "ubiquinone," Aberg clarifies that most, if not all, of the "ubiquinone" is present in the reduced form (*Id.*) Importantly, Aberg also isolated relative proportions of reduced $CoQ_9$ and reduced $CoQ_{10}$ in amounts that fall within the ranges recited in claim 5. (Taylor Decl., ¶ 38, Ex. 3 at ¶ 48, Ex. 8 at 232; Ex. 29 at 21:6-22:18).

**c. Claim 15 of the '080 Patent is not patent-eligible subject matter because it is directed toward a natural phenomenon because it is directed toward a generic method that results in the ineligible compound of claim 5.**

Claim 15 of the '080 recites a method that results in the composition of claim 5. (*See* '080 Patent at Col. 18, ll. 4-21). Claim 15 only recites two generically method steps: (1) a "providing" step; and (2) a "reducing" step. (*See* '080 Patent at Col. 18, ll. 6, 9). These broad and unspecified steps confer no distinction between the naturally occurring composition of claim 5, thereby causing claim 15 to begin and end with a natural phenomenon. *See Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015) ("The method therefore begins and ends with a natural phenomenon. Thus, the claims are directed to matter that is naturally occurring."). Claim 15 is thus

[4] When Aberg refers to Ubiquinone-9 and Ubiquinone-10, Aberg is referring to $CoQ_9$ and $CoQ_{10}$ as those terms are used in the '080 Patent. (Taylor Decl., ¶ 37, Ex. 3 at ¶ 47).

directed toward a natural phenomenon under step one of the *Alice*/*Mayo* framework.

Furthermore, under step two, even considering the combination of claim elements as a whole, the generic, unspecified, post-solution steps of "providing" and "reducing" fail to transform the ineligible composition recited in claim 15 into an inventive concept, along with the combination of claim elements as a whole. Also, as discussed with respect to claim 5, the '080 Patent itself admits that the recited steps were well-understood, routine, and conventional prior to the '080 Patent. (*See* '080 Patent at Col. 5, ll. 47-63). The step of "providing" $CoQ_9$, $CoQ_{10}$, and/or $CoQ_{11}$ is done by extraction and purification from a naturally occurring substance, reduction of oxidized $CoQ_9$ and oxidized $CoQ_{11}$ according to any suitable method, including those explicitly discussed in the prior art '044 Patent. (*Id.* at Col. 5, ll. 17-66). The '080 Patent also explains that the "reducing" step "can be performed according to the method described in [the '044 Patent] and the like." (*Id*. at Col. ll. 64-67). Additionally, the '080 Patent explains that the "step of separately preparing and adding (a) and/or (b) can be a step for adding (a) and/or (b) separately prepared as mentioned above. The preparation and addition can be performed by any suitable method known in the art." (*Id*. at Col. 6, ll. 24-28 (emphasis added)). Indeed, the '080 Patent's multiple admissions that the method of claim 15 is comprised of nothing more than well-understood, routine, and conventional techniques leaves no doubt that claim is ineligible under § 101.

**2. Claims 1 and 13 of the '044 Patent are invalid under 35 U.S.C. § 101 because they do not recite patent-eligible subject matter.**

Claims 1 and 13 of the '044 Patent are both ineligible under § 101 because they are both directed toward naturally occurring reduced $CoQ_{10}$. Although the claims recite crystalline ubiquinol, and a method of making that composition, the crystallization method is merely conventional.

**a. Claims 1 and 13 of the '044 Patent are directed toward a patent-ineligible natural product or natural phenomenon.**

Claim 1 of the '044 Patent recites a method for crystallizing reduced $CoQ_{10}$. (*See* '044 Patent at Col. 21, ll. 16-20). Claim 13 recites a reduced $CoQ_{10}$ crystal having reduced $CoQ_{10}$ to oxidized $CoQ_{10}$ weight ratio of not lower than 96/4. (*See Id.* at Col. 21, ll. 59-61). Based on the admissions of the '044 Patent, prior art, Kaneka's expert's opinions, Kaneka's submissions to the FDA, and Defendants' expert's opinion, it is well-understood that reduced $CoQ_{10}$ is a naturally occurring compound. (*See Id.* at Col. 1, ll. 43-60; Taylor Decl., ¶ 25, Ex. 3 at ¶ 36; Ex. 8 at Abstract, 232; Ex. 9 at Abstract; Ex. 10 at 267; Ex. 11 at 2169; Ex. 12 at Abstract; Ex. 7 at 5; Ex. 15 at 8-9). The "Background Art" section of the '044 Patent acknowledges that reduced CoQ10 is naturally occurring:

> It is known that reduced coenzyme $Q_{10}$ can be prepared by producing coenzyme $Q_{10}$ in the conventional manner, for example by synthesis, fermentation, or extraction from natural products, and concentrating a reduced coenzyme $Q_{10}$-containing eluate fraction resulting from chromatography (JP-A-10-109933). On that occasion, as described in the above-cited publication, the chromatographic concentration may be carried out after reduction of oxidized coenzyme $Q_{10}$ contained in the reduced coenzyme $Q_{10}$ with a conventional reducing agent such as sodium borohydride or sodium dithionite (sodium hyposulfite), or reduced coenzyme $Q_{10}$ may be prepared by reacting the reducing agent mentioned above with an existing highly pure grade of coenzyme $Q_{10}$ (oxidized form). However, the thus-obtained reduced coenzyme $Q_{10}$ cannot always be in a highly pure state but tends to occur as a low-purity crystalline, semisolid, or oily product containing such impurities as oxidized coenzyme $Q_{10}$.

('044 Patent at Col. 1, ll. 43-60. (emphasis added)). This statement in the '044 Patent comports with the knowledge in the prior art that existed as far back as the 1950s that $CoQ_{10}$ exists naturally, including in its reduced form. (*See, e.g.*, Taylor Decl., ¶ 23; Ex. 8 at Abstract, 232 ("All rat tissues contain appreciable amounts of ubiquinone."), Ex. 9 at Abstract, Ex. 10, Ex. 11 at 2169, Ex. 12 at Abstract, Ex. 15 at 8-9.)

Claim 13 generically recites a reduced coenzyme crystal with a proportion of reduced $CoQ_{10}$ to oxidized $CoQ_{10}$. (Taylor Decl., ¶ 26; '044 Patent at Col. 21, ll. 59-61). Reduced $CoQ_{10}$ exists in its pure form and is preferentially present in its reduced form in the body because that form is the one utilized by various metabolic processes and has improved bioavailability. (Taylor Decl., ¶ 30, Ex. 3 at ¶ 42; Ex. 13 at Col. 2, ll. 42-50).

Kaneka's expert, Dr. Myerson, testified that reduced and oxidized $CoQ_{10}$ occur naturally:

> Q: And I know earlier we talked about the presence of CoQ10, reduced and oxidized in animal tissue. So we can agree that those [compounds] occur naturally. Correct?
> A: They are present in animal tissue, that's correct.

(Taylor Decl., ¶ 107, Ex. 29 at 143:6-11). Considering Dr. Myerson's testimony in conjunction with the prior art references and the language of the '044 Patent, it is apparent claims 1 and 13 of the '044 Patent are directed toward reduced $CoQ_{10}$, a naturally occurring composition.

**b. There is no inventive concept in the '044 Patent.**

The second step of the *Alice* framework likewise cannot save the '044 Patent because the patent fails to "recite an inventive concept that transforms the observation of a natural phenomenon into a patentable invention." *Genetic Veterinary Sciences, Inc. v. LBOKLIN GmbH & Co. KG*, 933 F.3d 1302, 1318 (Fed. Cir. 2019). The '044 Patent explains that: "The reduced coenzyme $Q_{10}$ to be subjected to crystallization can be obtained in the conventional manner, for example, by synthesis, fermentation, or extraction from a natural source." ('044 Patent at Col. 12, ll. 44-47 (emphasis added)). The '044 Patent continues by saying that "[t]he method of crystallization is not particularly restricted but the crystallization can be carried out by utilizing a conventional crystallization method, namely at least one of the cooling crystallization, concentration crystallization, solvent substitution crystallization and other methods." (*Id.* at Col. 13, ll. 23-27 (emphasis added)). Further, claim 1 of the '044 Patent simply utilizes well-known solvents to

crystallize the reduced Coenzyme $Q_{10}$ in the recited conventional manner. (Taylor Decl., ¶ 28). To the extent that Kaneka purports that claim 1 requires any particular non-conventional crystallization steps, these are neither recited in the claim nor elucidated in the specification. In fact, Kaneka's expert, Dr. Myerson, testified that each of the solvents specified in claim 1 of the '044 Patent—that is, hydrocarbons, fatty acid esters, ethers, and nitriles—is conventionally used for crystallization:

> Q: Were hydrocarbons used conventionally in [the] crystallization processes before the filing of the '044 Patent?
> A: Hydrocarbons in general?
> Q: Yes.
> A: Sure, yes.
> Q: Were fatty acid esters used to crystallize components in solutions prior to the filing of the '044 Patent?
> A: Less commonly, but I would assume we could find a reference that used the fatty acid ester to crystallize something.
> Q: Were ethers used to crystallize components from solution prior to the filing date of the "'044 Patent?
> A: Yes, I would think you could find references that have ethers being used.
> Q: What about nitriles?
> A: Same answer.

(Taylor Decl., ¶ 107, Ex. 29 at 148:8-24; 149:1-2). Regardless of which solvent is used to crystallize $CoQ_{10}$, all of the solvents listed in claim 1 of the '044 Patent were well-known and well-understood at the time the '044 Patent was filed. *See Genetic Veterinary Sci.*, 933 F.3d at 1319 (finding claims did not recite an inventive concept where patent-owner's expert testified that the methods recited in the claim were well-known and used for years); *Mayo*, 566 U.S. at 82 ("[S]imply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable."); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1362 (Fed. Cir. 2017) (finding patents were "directed to patent-ineligible subject matter" because the patents' specifications described the techniques as well-understood and conventional and because

"transforming claims that are directed to a law of nature requires more than simply stating the law of nature while adding the words 'apply it'"). For at least the foregoing reasons, claims 1 and 13 of the '044 Patent are invalid under § 101.

**3. Kaneka's submissions to the FDA describing its ubiquinol products as natural products leave any rebuttal to § 101 untenable.**

As discussed above, Kaneka has made NDIN submissions to the FDA, which assert that the ubiquinol contained in Kaneka's commercial products are natural products. (*See supra* § III. A; Taylor Decl., ¶ 62, Ex. 15 at 8-9). Kaneka's representations made to the FDA is further evidence that the asserted claims in the '044 Patent and '080 Patent are directed to natural products, and the natural products are exposed to nothing more than well-known, routine, and conventional post-solution activity. (*Id.*) Accordingly, notwithstanding that the Patents-in-Suit are directed toward patent-ineligible subject matter, Kaneka's admissions to the FDA support that Defendants are entitled to summary judgment of invalidity under 35 U.S.C. § 101.

**C. The Patents-in-Suit are invalid under 35 U.S.C. § 102, or, in the alternative, under 35 U.S.C. § 103**

Kaneka's four asserted claims are invalid for anticipation or obviousness. A claimed invention is anticipated, and is therefore not novel, under 35 U.S.C. § 102 if it "was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant" or "was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. §§ 102(a)-(b).[5] "To show that a patent claim is invalid as anticipated, the accused infringer must show by clear

[5] Defendants refer to the versions of 35 U.S.C. §§ 102 and 103 that were in force prior to the enactment of the America Invents Act, and which are applicable here. *See, e.g.*, *Solvay S.A. v. Honeywell Int'l Inc.*, 742 F.3d 998, 1000 n.1 (Fed. Cir. 2014).

and convincing evidence that a single prior art reference discloses each and every element of a claimed invention." *Silicon Graphics, Inc. v. ATI Tech., Inc.*, 607 F.3d 784, 796 (Fed. Cir. 2010). "The anticipation analysis asks solely whether the prior art reference discloses and enables the claimed invention, and not how the prior art characterizes that disclosure or whether alternatives are also disclosed." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1376 (Fed. Cir. 2005) (quoting *Hewlett Packard Co. v. Mustek Sys.*, 340 F.3d 1314, 1324 n.6 (Fed. Cir. 2003). "While anticipation is a question of fact, it may be decided on summary judgment if the record reveals no genuine dispute of material fact." *Encyclopaedia Britannica, Inc. v. Alpine Elecs. of Am., Inc.*, 609 F.3d 1345, 1349 (Fed. Cir. 2010) (cleaned up).

Under 35 U.S.C. § 103(a), a patent claim is invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." "Obviousness is a question of law based on underlying factual findings: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) objective considerations of nonobviousness." *In re Morsa*, 713 F.3d 104, 109 (Fed. Cir. 2013) (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966)).

To establish obviousness, a party "'must demonstrate by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.'" *TQ Delta LLC v. 2Wire, Inc.*, 2021 WL 3145655, at *3 (D. Del. July 26, 2021) (quoting *InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1347 (Fed. Cir. 2014)). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550

U.S. 398, 416 (2007). "The motivation [to combine] need not be found in the references sought to be combined, but may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself." *Dystar Textilfarben GMBH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006). "'[T]here is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art.'" *Dystar Textilfarben GMBH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006) (quoting *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1472 (Fed. Cir. 1997)). In this case, the Patents-in-Suit are rendered invalid under both § 102 and § 103.

**1. The '044 Patent is invalid as lacking novelty, or, in the alternative, as obvious.**

Claim 1 of the '044 Patent describes. "a method of crystallizing reduced Coenzyme $Q_{10}$ which comprises crystallizing the reduced Coenzyme $Q_{10}$ using, as a solvent, at least one species selected from the group consisting of hydrocarbons, fatty acid esters, ethers and nitriles." ('044 Patent at Col. 21, ll. 16-20). Claim 13 of the of the '044 Patent recites: "A reduced coenzyme $Q_{10}$ crystal with a reduced coenzyme $Q_{10}$/oxidized coenzyme $Q_{10}$ weight ratio of not lower than 96/4." (*Id.* at Col. 21, ll. 59-61).

To begin, crystallization has been used by chemists to produce purified compounds for centuries. For example, one of the earliest texts on crystallization, published in 1748, describes methods to produce crystals from various natural sources (Taylor Decl., ¶ 66, Ex. 16 at 189). Modern crystallization of organic molecules was discovered as early as 1840 (Taylor Decl., ¶ 66, Ex. 17). The "Background Art" section of the '044 Patent recites that $CoQ_{10}$ is naturally occurring,

is reduced using conventional methods, and crystalline forms were known to be produced according to prior art methods:

> It is known that reduced coenzyme $Q_{10}$ can be prepared by producing coenzyme $Q_{10}$ in the conventional manner, for example by synthesis, fermentation, or extraction from natural products…. However, the thus-obtained reduced coenzyme $Q_{10}$ cannot always be in a highly pure state but tends to occur as a low-purity crystalline, semisolid, or oily product containing such impurities as oxidized coenzyme $Q_{10}$.

('044 Patent at Col. 1 ll. 43-60). As such, the '044 Patent admits that the process of producing crystalline reduced $CoQ_{10}$ in the manner described and claimed in the '044 Patent was known in the prior art before the priority date of the '044 Patent.

Beyond the '044 Patent's admissions, the scope and content of the prior art is replete with references that teach industrial production of $CoQ_{10}$ to produce a final, crystallized product. A person of skill in the art would understand that the combined teachings of such references yield predictable results for producing crystallized $CoQ_{10}$. In particular, a person of skill in the art would look to prior art to produce crystalline $CoQ_{10}$. In one report on the creation of pure, crystalline $CoQ_{10}$, Page reported its isolation from bacterial cells and production of crystals. (Taylor Decl., ¶ 97, Ex. 19 at 318-321). Page specifically carried out crystallization of bacterial $CoQ_{10}$ to confirm its identity compared to beef heart $CoQ_{10}$ and found this resulted in crystals with identical properties to beef heart $CoQ_{10}$ (*Id.*)

In another early report, Folkers teaches that $CoQ_{10}$ recovered from fermentation can be purified from acetone or ethanol: "Substantially pure Coenzyme $Q_{10}$ thereby obtained as an orange-yellow solid melting in the range of 47-50°C. Such crystalline preparations are recognized as pure Coenzyme $Q_{10}$…." (Taylor Decl., ¶ 98, Ex. 22 at 4:27-29). Claim 13 of Folkers cites $CoQ_{10}$ crystals as the final product of the production of CoQ10 as described in the patent. (*Id.* at 12:27-32). In another example, Yoshida isolated $CoQ_{10}$ from various bacteria by standard fermentation

methods (Taylor Decl., ¶ 99, Ex. 23 at 20). After purification of $CoQ_{10}$ from the fermentation broth, the $CoQ_{10}$ was crystallized from ethanol for further analysis (*Id.*)

Crane describes the extraction of CoQ analogs 6 through 10 from animal tissues. (Taylor Decl., ¶100, Ex. 10 at 269). After extraction and purification, $CoQ_{10}$ can be isolated from alcohol-ether or acetone extracts. (*Id.*) Crane explains that $CoQ_{10}$ can be purified using an extraction using an "ethanole-ether (sic)" mixture, which is then crystallized. (*Id.*) Thus, Crane shows that one of ordinary skill in the art would have would have understood how to crystallize $CoQ_{10}$ formulations using an ether, such as the one specified in claim 1 of the '044 Patent.

Shigeru describes a method for preparing $CoQ_{10}$ from bacteria and producing crystalline $CoQ_{10}$ by crystallization from hydrophilic solvents including methanol and ethanol. (Taylor Decl., ¶ 101, Ex. 24 at Col. 5). Likewise, Nisshin describes purifying reduced $CoQ_{10}$ from fermentation or by synthesis, wherein the reduced $CoQ_{10}$ is crystallized using acetone. (Taylor Decl., ¶ 102, Ex. 25 at 3, ll. 21-29). And Kondo claims production of $CoQ_{10}$ from various bacteria. (Taylor Decl., ¶ 103, Ex. 26 at Col. 2, l. 45 – Col. 3, l. 33; Col. 4, l. 55 – Col. 5, l. 4; Col. 5, l. 28 – Col. 6, l. 4). Kondo identifies the final product in examples 1, 2, 4, 7, 8 and 9 as crystalline $CoQ_{10}$ and cites, in Claim 3 of the patent: "A method as set forth in Claim 1, wherein said Coenzyme $Q_{10}$ is recovered in the form of crystals." (*Id.*)

Other Coenzyme Q molecules have also been crystallized. For example, Aida describes crystallization of Coenzyme $Q_{10}$, $Q_9$, and $Q_8$, isolated from Pseudomonas sp. (Taylor Decl., ¶ 104, Ex. 18 at Col. 3, ll. 30-65, Col. 4, l. 64-Col. 5, l. 44). Aida explains that reduced $CoQ_9$ crystals can be formed using an ether, such as petroleum ether. (*Id.*) Similarly, Chopra teaches a method where conditions are present to crystallize reduced $CoQ_{10}$ using medium chain triglycerides as a solvent, wherein the solvent is heated, and then cooled. (Taylor Decl., ¶ 71, Ex. 26 at Ex. 13 at Col. 9, ll.

29-65). In his deposition, Dr. Myerson explained that such as those described in Chopra are the conditions that could result in supersaturation, which leads to crystallization. (Taylor Decl., ¶ 74). Although Chopra does not expressly state that the recited process would likely produce a crystalline product, or that could be readily modified utilizing the conventional crystallization techniques of the prior art, Chopra describes a process that Dr. Myerson recognizes as one that could lead to crystallization.

Moreover, Chopra teaches a reduced $CoQ_{10}$ composition that is "substantially ubiquinone-free," meaning that it contains "virtually no" ubiquinone, or the composition contains ubiquinol and ubiquinone in a ratio of no less than, for example, 19:1 or 99:1. (Taylor Decl., ¶ 71, Ex. 26 at Ex. 13 at Col. 7, ll.31-40). Thus, Chopra teaches how to produce a ubiquinol composition that would read on the limitation of claim 13 of the '044 Patent, reciting "a reduced coenzyme $Q_{10}$/oxidized coenzyme $Q_{10}$ weight ratio of not lower than 96/4." Additionally, to the extent that Chopra does not demonstrate that claim 13 of the '044 Patent lacked novelty, it would have been obvious to produce a crystalline product because the skilled artisan would have understood at the time of the alleged invention of the '044 Patent that crystallization was an effective way to maintain the purity of the desired product, which Chopra specifies to be as pure as 99:1 ubiquinol to ubiquinone. And, since the '044 Patent itself admits that the methods for producing crystals were nothing more than "conventional crystallization methods," there was nothing non-obvious about the crystallization process employed by the '044 Patent. ('044 Patent Col. 13, ll. 23-27).

Furthermore, it would have been obvious to the skilled artisan at the time of the invention of claims 1 and 13 of the '044 Patent to crystallize reduced $CoQ_{10}$ using known methods because crystallization provides several well-known benefits such as increasing purity, improving pouring, and reducing caking in the packaging:

> Crystallization is a process where solid particles are formed from a homogenous phase. This process can occur in the freezing of water to form ice, in the formation of snow particles from a vapor, in the formation of solid particles from a liquid melt, or in the formation of solid crystals from a liquid solution. The last process mentioned, crystallization from a solution, is the most important one commercially and will be treated in the present discussion. In crystallization the solution is concentrated and usually cooled until the solute concentration becomes greater than its solubility at that temperature. Then the solute comes out of solution, forming crystals of approximately pure solute.
>
> In commercial crystallization not only are the yield and purity of the crystals important but also the sizes and shapes of the crystals. It is often desirable that crystals be uniform in size. Size uniformity is desirable to minimize caking in the package, for ease of pouring, for ease in washing and filtering, and for uniform behavior when used.

(Taylor Decl., ¶ 105, Ex. 27 at 737).

Indeed, the ordinarily skilled artisan would have known and been motivated to employ the conventional crystallization techniques described by the ’044 Patent (such as cooling and evaporation) to improve purity of the desired compound:

> Crystallization, (15), is carried out in many organic, and almost all inorganic, chemical manufacturing plants where the desired product is a finely divided solid. Since crystallization is essentially a purification step, the conditions in the crystallizer must be such that impurities do not precipitate with the desired product. In solution crystallization, the mixture, which includes a solvent, is cooled and/or the solvent is evaporated to cause crystallization.

(Taylor Decl., ¶ 106, Ex. 28 at 13).

Therefore, considering the prior art, the state of the art as would have been understood by one of ordinary skill in the art at the time of the ’044 Patent, and the explicit admissions of the conventional elements of claims 1 and 13 of the ’044 Patent, claims 1 and 13 of the ’044 Patent either lack novelty, or in the alternative, would have been obvious.

**2. The ’080 Patent is invalid as lacking novelty, or, in the alternative, as obvious.**

Claims 5 and 15 of the ’080 Patent lack novelty or are obvious in view of the prior art. Claims 5 and 15 are drawn toward reduced $CoQ_{10}$ compositions, wherein the compositions may contain some proportion of $CoQ_9$ and/or $CoQ_{11}$.

As discussed above, the ’080 Patent admits that all of the compositions and methods described and claimed in the patent can be achieved utilizing the teachings and methods of the prior art ’044 Patent. To the extent the ’080 Patent is not rendered invalid by these admissions regarding the prior art of the ’044 Patent, Dr. Myerson explained that production of reduced $CoQ_{10}$ starting with oxidized $CoQ_{10}$ would produce the claimed amounts of CoQ homologs contained in claims 5 and 15 of the ’080 Patent: “The defendants are producing a reduced $CoQ_{10}$ composition starting with oxidized coenzyme $Q_{10}$ (and thus oxidized $Q_9$ and $Q_{11}$) and therefore meet this claim element (see Exhibit E).” (Taylor Decl., Ex. 6 at ¶ 112 (citing to a document explaining DFH’s process for making DuoQuinol)). Thus, if Dr. Myerson’s contention concerning infringement could be taken as true, this also means that all prior art reduction of $CoQ_{10}$ from oxidized $CoQ_{10}$ would necessarily anticipate and therefore invalidate claims 5 and 15 of the ’080 Patent.

Aida describes crystallization of Coenzyme $Q_{10}$, $Q_9$, and $Q_8$, isolated from *Pseudomonas* sp. (Taylor Decl., ¶¶ 80, 104, Ex. 18 at Col. 3, ll. 30-65, Col. 4, l. 64 – Col. 5, l. 44). The human body contains both Coenzymes $Q_{10}$ and $Q_9$. (Taylor Decl., ¶ 81). In fact, some microorganisms produce Coenzymes $Q_6$, $Q_7$, $Q_8$, or $Q_9$. (*Id.*)

Reduced $CoQ_{10}$ and $CoQ_9$ exist naturally in combination in human tissues in the proportions recited by claims 5 and 15 of the ’080 Patent. (Taylor Decl., ¶ 83). Table III of Aberg displays a series of extracted tissue sample results. (Taylor Decl., ¶ 38, Ex. 8 at 232). For example, Aberg includes a sample of pancreatic tissue extracted from a human, where the sample contains 1.6 +/- 0.2 µg/g tissue of Ubiquinone-9 and 32.7 +/- 2.8 µg/g. (*Id.*) Aberg also states that “[i]n the case of the human liver pancreas, and intestine, the ubiquinone isolated was completely reduced…” (*Id.* at ¶ 39). Thus, the Ubiquinone-9 and Ubiquinone-10 values for human pancreatic

tissue listed in Table III is entirely in the reduced form, thereby allowing for comparison of the relative amounts of reduced $CoQ_9$ and $CoQ_{10}$ in the sample.

Although there is ambiguity regarding the interpretation of the relative amounts of Coenzyme Q homologs recited in claims 5 and 15 of the ’080 Patent., Dr. Myerson proffered in his Rebuttal Report regarding Invalidity and during his deposition, that a prior art reference need only satisfy three criteria to anticipate claims 5 and 15 of the ’080 Patent:

> Q: So I just want to -- maybe I can sum – I think there is sort of three criteria we just established for claim 5 of the '080 patent, and maybe we can summarize them. If you can agree with me, then we can move on. So the first criteria, I think, is that the reduced $CoQ_{10}$ need not be less than 0.01 percent as a proportion of the total composition. Correct?
> A: Correct.
> Q: And then I think the next criteria is that if I take the amount of reduced $CoQ_9$ and then divide that by the amount of reduced $CoQ_{10}$, that resulting amount needs to be somewhere between 1.5 and 99 weight percent. Correct?
> A: Correct.
>
> ****
>
> Q: The third criteria is that there must be less than 10 percent of oxidized $CoQ_{10}$ when you take the amount of oxidized $Q_{10}$ and divide that by the sum of the oxidized $CoQ_{10}$ and reduced $CoQ_{10}$. Correct?
> A: Right. So, of course, the claim expresses it differently, meaning -- it says at least 90 percent of. You did it the opposite way, but it means the same thing.

(Taylor Decl., Ex. 29 at 21:6-22:14). Following this line of questioning, Dr. Myerson was asked to relate the values for $CoQ_9$ and $CoQ_{10}$ for the samples that produced the values shown in Table III of Aberg. (*Id.* at 42:16-24). In doing so, Dr. Myerson testified that the human pancreatic tissue sample containing relative amounts of reduced $CoQ_9$ to reduced $CoQ_{10}$ satisfy the three criteria to anticipate claims 5 and 15 of the ’080 Patent:

1. The sample composition of human pancreatic tissue shown in Table III of Aberg contains 95.3% reduced $CoQ_{10}$ (*Id.* at 45:20-46:23). This means the amount of reduced $CoQ_{10}$ was greater than 0.01 percent in the sample analyzed using HPLC.

2. The amount of reduced $CoQ_9$ relative to the amount of reduced $CoQ_{10}$ is 4.9 percent (*Id.* at 58:15-24).
3. The sample composition containing $CoQ_{10}$ was entirely reduced $CoQ_{10}$ (i.e. 100%), so there would not be less than 90% of reduced $CoQ_{10}$ as a proportion of the sum of reduced $CoQ_{10}$ and oxidized $CoQ_{10}$. (*Id.* at 56:24-57:9).

Therefore, Aberg teaches all of the limitations of claim 5 under the framework proposed by Myerson. And because Aberg actually made the sample that was analyzed via HPLC and used to find the relative amounts of reduced $CoQ_9$ and CoQ10, Aberg also practiced the method of claim 15. (*See* '080 Patent at Col. 18, ll. 4-21).

Although there is ambiguity regarding the interpretation of the relative amounts of Coenzyme Q homologs listed in claims 5 and 15 of the '080 Patent, claims 5 and 15 are anticipated in view of at least Aberg. Dr. Taylor's secondary interpretation of claims 5 and 15 differs from Dr. Myerson's in that it explains that the relative amount of $CoQ_9$ can be interpreted as it is calculated in the specification's examples, i.e., where the amount of coenzyme $Q_9$ is calculated as ($Q_9$/($Q_9$ + $Q_{10}$)). *Id*. The ubiquinone sample from human pancreatic sample extracted by Aberg provides 1.6 +/- 0.2 µg/g tissue of reduced Ubiquinone-9 and 32.7 +/- 2.8 µg/g reduced Ubuiquinone-10, thereby providing a relative amount of reduced Ubiquinone-9 by of 1.6 µg/(1.6 µg +32.7 µg) * 100, i.e., 4.7 weight percent. (Taylor Decl., ¶ 38, Ex. 8 at 232). Thus, Aberg anticipates element two identified above, thereby anticipating the compositions of claims 5 and 15 under either interpretation.[6]

To the extent that it could be considered that Aberg did not actually make the composition of the samples shown in Table III, the steps of claim 15 lack any specificity and do no more than

[6] Defendants do not dispute the stipulated claim constructions entered in this case setting forth the plain and ordinary meaning of the claim terms. (D.I. 55). However, Defendants contend that claims 5 and 15 are indefinite due to the multiple, broad, interpretations that fail to reasonably inform the skilled artisan as to the scope of the claims. *See infra* at § IV.D.2. Accordingly, Defendants address both interpretations for the sake of novelty to demonstrate their lack of inventiveness.

simply recite generic, unspecified method steps that fail to confer any validity over claim 5. Consequently, the analysis of claim 15 in view of the prior art is the same as that of claim 5 and, as a result, claim 15 lacks novelty and is obvious for the same reasons as claim 5. Further, to the extent that it could be concluded that claim 5 or claim 15 does not lack novelty in view of Aberg, an alleged invention can be found obvious when the invention does no more than combine prior art elements according to known methods to yield predictable results. *See KSR Int'l Co.*, 550 U.S. at 416. As such, it would have been obvious to arrive at the claimed amounts of $CoQ_9$ and $CoQ_{10}$ because these amounts would have been produced by combining known $CoQ_9$ and $CoQ_{10}$ sources to produce compositions with the claimed ranges in a predictable manner. One of ordinary skill in the art would have understood how to select the appropriate starting materials, combined with the understanding that $CoQ_9$ and $CoQ_{10}$ could be independently synthesized and combined in a predictable manner, so it would have been obvious to one of ordinary skill in the art to have arrived at claims 5 and 15 of the ’080 Patent. (Taylor Decl., ¶ 110.)

At minimum, the foregoing demonstrates that the subject matter of the claim 5 and claim 15 of the ’080 Patent fail to contain anything inventive, and either lack novelty, or would be rendered obvious by the prior art. Consequently, claims 5 and 15 of the ’080 Patent are invalid under § 102 and § 103.

**D. Claims 5 and 15 of the ’080 Patent are invalid under 35 U.S.C. § 112.**

**1. The ’080 Patent is unpatentable for lack of enablement and for lacking sufficient written description.**

Section 112’s written description requirement in place at the time of the filing of the ’080 Patent demands that the specification “clearly allow[s] persons of ordinary skill in the art to recognize that the inventor invented what is claimed.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (cleaned up). “In other words, the test for sufficiency is whether

the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* "Whether a claim satisfies the enablement requirement of 35 U.S.C. § 112 is a question of law . . . , although the determination may be based on underlying factual findings . . . ." *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1188 (Fed. Cir. 2014). To the extent that Kaneka attempts to assert that the claimed proportions of claims 5 and 15 are somehow the result of specific, non-obvious interventions or inventive methods that make the claims inventive (they are not), then the '080 Patent is invalid under the written description and/or enablement requirements.

**2. The '080 Patent is unpatentable for lack of definiteness.**

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). A claim term "is indefinite if its language 'might mean several different things and no informed and confident choice is available among the contending definitions.'" *Media Rights Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1371 (Fed. Cir. 2015) (quoting *Nautilus*, 572 U.S. at 911 n.8). Indefiniteness is appropriately handled on summary judgment because it is a question of law. *See Eli Lilly Co. v. Teva Parenteral Med., Inc.*, 845 F.3d 1357, 1370 (Fed. Cir. 2017) ("Indefiniteness is a question of law . . . ."). "A claim is indefinite if its legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular composition infringes or not." *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003).

The amount of reduced $CoQ_{10}$ is recited as "the proportion of reduced coenzyme $Q_{10}$ relative to the total amount of coenzyme $Q_{10}$ [which is] not less than 90 wt %." ('080 Patent at Col. 18, ll. 19-21). The indefiniteness of claims 5 and 15's usage of "the total amount of Coenzyme

$Q_{10}$" is demonstrated by the '080 Patent specification's statement that "reduced coenzyme $Q_{10}$ can contain oxidized coenzyme $Q_{10}$." (*Id.* at Col. 4, l. 64). The recitation that "the total amount of coenzyme $Q_{10}$" thus renders claims 5 and 15 indefinite. Furthermore, Dr. Myerson proposes one interpretation of the limitation of "not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme $Q_9$ relative to reduced coenzyme $Q_{10}$" is calculated as the amount of reduced CoQ9 divided by the amount of reduced CoQ10 multiplied by 100 to obtain the weight percent. (Taylor Decl., ¶ 118). However, Dr. Taylor identifies another interpretation, which accords with the examples in the specification, where $Q_9$ equals ($Q_9$/($Q_9$ + $Q_{10}$)) multiplied by 100 to obtain the weight percent. (*Id.*) For at least these reasons, the skilled artisan could not ascertain, with reasonable certainty, the scope and meaning of claims 5 and 15 of the '080 Patent.

**E. The Court Should Grant Summary Judgment on Kaneka's Lost Profits Claim.**

Kaneka contends that it is entitled to recover lost profits from Defendants' sale of the Accused Products. "Whether lost profits are legally compensable in a particular situation is a question of law." *Poly-Am. L.P. v. GSE Lining Tech.*, Inc., 383 F.3d 1303, 1311 (Fed. Cir. 2004). While a patent owner may recover lost profits for infringement of a patent under certain circumstances, it "may not claim, as its own damages, the lost profits of a related company." *See, e.g.*, *Warsaw Orthopedic, Inc. v. NuVasive,* Inc., 778 F.3d 1365, 1375 (Fed. Cir. 2015), vacated on other grounds, 136 S.Ct. 893 (2016). Instead, the Federal Circuit has made clear that "the lost profits must come from the lost sales of a product or service that patentee itself was selling." *Id.* at 1376; *see also Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1365-67 (Fed. Cir. 2008) (refusing to award lost profits to the patent holder when its subsidiary corporation lost sales due to infringement despite the fact that the parent and subsidiary maintained consolidated financial statements), mandate recalled and amended on other grounds, 557 F.3d 1377 (Fed. Cir. 2009); *Poly-America*, 383 F.3d at 1311 ("the patentee needs to have been selling some item, the profits

of which have been lost due to infringing sales, in order to claim damages consisting of lost profits."); *Mars, Inc. v. TruRx LLC*, 2016 WL 4061981, at *2 (E.D. Tex. Apr. 29, 2016) (Federal Circuit cases "plainly recognize that in order to recover lost profits damages, the lost profits must come from the lost sales of a product the patentee itself was selling" and the patentee cannot recover lost profits on the products at issue "because Mars itself does not sell those products.").

Here, plaintiff Kaneka alleges it is a Japanese corporation and owns the Patents-in-Suit. (D.I. 75 ⁋⁋ 3, 15-16), but it does not sell any relevant product. Kaneka erroneously attempts to recover the lost profits of its subsidiary Kaneka North America LCC ("KNA").[7] Kaneka granted KNA a [redacted] to use the Patents-in-Suit, a fact confirmed by Kaneka's Rule 30(b)(6) witness, Iwao Funahashi. (Declaration of Richard J. Oparil ("Oparil. Decl."), ¶ 6, Ex. D at 80:15-81:12). In consideration for the license, KNA paid Kaneka [redacted]. (Oparil Decl., Exs. E, F, G). Kaneka's damages expert, Sam Rosenfarb, confirmed that Kaneka was entitled to [redacted]. (Oparil Decl., Ex. H at 86:14-87:6).

Notwithstanding that Kaneka was entitled to the [redacted], Rosenfarb's calculation of lost profits relied solely on KNA's sales of Ubiquinol to DFH to calculate Kaneka's lost profits. (Oparil Decl., Exs. I, J). Rosenfarb advances a damages theory that Kaneka should be paid lost profits because DFH did not purchase Ubiquinol from Kaneka. (Oparil Decl., Ex. I ¶¶ 39-41). Yet, Kaneka and its expert ignore the undisputed fact that Kaneka has not and does not sell Ubiquinol. Instead, customers exclusively purchase Ubiquinol from Kaneka's indirect subsidiary, KNA. And nowhere in his reports does Rosenfarb indicate that Kaneka made any

[7] KNA (formerly Kaneka Nutrients L.P.) is twice removed from Kaneka Corporation, the Plaintiff in this action. Specifically, KNA, a Texas limited liability company, is a subsidiary of Kaneka Americas Holding, Inc. Kaneka Americas Holding, Inc. is a subsidiary of Kaneka Corporation.

profits from sales by KNA. Rosenfarb's testimony confirms that Kaneka only earned the [redacted]. (Oparil Decl., Ex. H 86:14-87:6). This evidence is fatal to Kaneka's ability to recover lost profits. *See, e.g., Mars, Inc.*, 527 F.3d at 1365-67 (patentee could not recover the lost profits of its subsidiary where they had a "traditional royalty-bearing license agreement" providing for royalty payments and there was no record evidence that it ever received or was entitled to receive any profits).

"[T]he Federal Circuit has explained that two companies that benefit from dividing patent ownership from sale of the patented product must also accept the consequence that the patent owner will be unable to claim the lost profits experienced by the seller." *Intuitive Surgical, Inc. v. Auris Health, Inc.*, No. 18-1359-MN, 2021 WL 3662842, at *3 (D. Del. Aug. 18, 2021) (granting summary judgment to defendant where patent-owner could not show entitlement to lost profits and only provided a conclusory statement that profits flowed inexorably to the patent-owner). In this case, Kaneka has failed to establish that any profits flow to it from KNA's sale of products from the Patents-in-Suit, and, in fact, has admitted that it only [redacted]. Accordingly, Kaneka is precluded as a matter of law from seeking lost profits and summary judgment should be granted.[8]

In the alternative, Defendants request that the Court exclude any testimony from Rosenfarb related to Kaneka's lost profits on the grounds that such testimony would be legally erroneous and

[8] *See, e.g., Trell v. Marlee Elecs. Corp.*, 912 F.2d 1443, 1445 (Fed. Cir. 1990) (patentee could not obtain damages based on lost profits as he did not himself manufacture and sell the device); *Novozymes A/S v. Genencor Int'l, Inc.*, 474 F. Supp. 2d 592, 605 (D. Del. 2007) (patentee may not recover lost profits of its subsidiary because "[the patent-owner] may not blur the legal distinction between itself and [its subsidiary] to recover damages that [the patent-owner] has not directly suffered"); *Illinois Tool Works, Inc. v. Seattle Safety, LLC*, 2010 WL 11523620, at *13 (W.D. Wash. Oct. 13, 2010) (precluding the recovery of lost profits to a patentee where a wholly-owned subsidiary, not the patentee, sold the accused products).

unhelpful and confusing to a jury.[9]

### F. Kaneka is not entitled to injunctive relief or ongoing damages for the expired '044 Patent.

Kaneka's Second Amended Complaint seeks injunctive relief and damages "for past and future infringing sales" on both patents-in-suit. (D.I. 75 at 12-13). However, Kaneka's '044 patent expired on September 12, 2022. As a result, Kaneka's request for an injunction on that patent is moot. *See, e.g.*, *Douglas Dynamics, LLC v. Buyers Products Co.*, 717 F.3d 1336, 1339 (Fed. Cir. 2013) ("Because the '530 patent has expired, any permanent injunction as to this patent is now moot, and the ongoing royalty ceases to apply after the date of expiration."); *Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 681 n.1 (Fed. Cir. 1990). Because the '044 patent has expired, Kaneka is not legally entitled to the relief requested and summary judgment in Defendant's favor is appropriate.

## V. MOTIONS TO EXCLUDE PLAINTIFF'S EXPERTS' OPINIONS

### A. Legal Standard

The admissibility of expert testimony in federal courts is governed by Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 592 n.10 (1993). Federal Rule of Evidence 702 sets out the requirements for expert witness testimony and states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and

[9] Rosenfarb testified that a lost profits analysis under Panduit includes "whether or not the patentholder has the capacity to make the product" and "whether profits can be calculated…." (Oparil Decl., ¶ 10, Ex. H at 5:5-11). But Rosenfarb simply assumed that KNA had the capacity to supply DFH based on a visit to KNA's Texas plant six years ago in connection with his expert work for Kaneka in a different case. (*Id.* at 54:2-57:10). As discussed above, his expert reports opine on KNA's lost profits, not Kaneka's. Rosenfeld has not conducted a proper evidence-based lost profits analysis using the relevant legal factors. His testimony should be excluded under *Daubert*.

> methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

"*Daubert* requires the district court to act as 'gatekeeper' and to assure that the scientific methodology upon which the expert opinion is founded is reliable." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 732 (3d Cir. 1994). When considering whether expert testimony is reliable, the *Daubert* court instructed trial courts to consider: (1) "whether the theory or technique employed by the expert is generally accepted in the scientific community;" (2) whether "it's been subjected to peer review and publication;" (3) "whether it can be and has been tested;" and (4) "whether the known or potential rate of error is acceptable." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 593-95 (1993). To that end, "[w]hether an expert has accounted for alternative explanations is a factor a court may consider in making the admissibility determination." *Tristrata Tech., inc. v. Mary Kay, Inc.* 423 F. Supp. 2d 456, 464 (D. Del. 2006). Most importantly, the party offering expert testimony bears the burden of proving its admissibility by a preponderance of the evidence. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 592 n.10 (1993).

**B. Dr. Myerson's expert report and reply should be excluded as unreliable.**

Dr. Myerson's expert report and reply should be excluded as unreliable for three primary reasons: (1) Dr. Myerson relies on an improper claim construction of "hydrocarbon" in forming his opinions; (2) Dr. Myerson bases his opinions on improper sample preparation and analysis; and (3) Dr. Myerson reaches inconsistent conclusions between his expert report and reply report.

**1. Dr. Myerson bases his opinion on an improper claim construction**

Throughout his report and reply, Dr. Myerson used claim constructions that deviated from the claim constructions stipulated by the parties and as disclosed in the patent. (*See generally* Taylor Decl., Exs. 6, 31). For example, Dr. Myerson's initial infringement report relies solely on "MCT Oil" to satisfy the "hydrocarbon" element of claim 1 of the '044 Patent but MCT oil is not

a hydrocarbon as stipulated by the parties. (Taylor Decl., ¶ 74, Ex. 6 at ¶ 92). The parties agreed to construe "hydrocarbon" using its plain and ordinary meaning—that is, "A chemical compound whose basic skeleton consists only of carbon and hydrogen, or of carbon and halogen (i.e., halogenated hydrocarbons)." (D.I. 55 at 2.) Dr. Myerson's use of "hydrocarbon" conflicted with the parties' stipulated claim construction, yet it formed the basis for a critical aspect of Kaneka's infringement theory. And, where an expert's understanding of a term deviates from the agreed-upon definition, his testimony related to the claim term should be excluded to prevent confusing a jury. *See CytoLogiz Corp. v. Ventana Med. Sys. Inc.*, 424 F.3d 1168, 1172 (Fed. Cir. 2005) ("The risk of confusing the jury is high when experts opine on claim construction . . . ."); *see Marctec, LLC v. Johnson & Johnson*, No. 07-cv-825-DRH, 2010 WL 680490, at *4 (S.D. Ill. Feb. 23, 2010) ("This Court excluded expert testimony premised on this mischaracterization of the claim construction as inadmissible under *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579 ... (1993) and Fed. R. Evid. ("FRE") 702 because it 'd[id] not address the requirements of the Court's claim construction and is irrelevant to the question of infringement.'"). Dr. Myerson's ignorance of the claim construction seriously undermines the reliability of his opinions.

**2. Dr. Myerson bases his opinions on improper sample preparation.**

To analyze the Accused Products, Dr. Myerson requested that an independent laboratory, Curia Global, test Defendants' CoQnol and Q10.1 products for the presence of crystalline or crystalline fragments of reduced $CoQ_{10}$. (Taylor Decl., Ex. 6 at ¶ 74). Dr. Myerson contended that the presence of crystalline or crystalline fragments of reduced $CoQ_{10}$ in the Accused Products meet the crystallizing aspects of the of the '044 Patent. (*Id.* at ¶ 92). Curia conducted a number of tests on Defendants' softgel capsules of the CoQnol and Q10.1 products, in part to determine the presence and amount of crystalline reduce CoQ10. (*Id.* at ¶¶ 74, 75). Dr. Myerson relied on Curia's testing and analysis of the Accused Products to form his opinions. (*Id.* at ¶¶ 80-84, 87-90).

However, Dr. Myerson did not provide any of the sample preparation protocols or analytical protocols used by Curia. (Taylor Decl., Ex. 29 at 170:9-171:4). In fact, the sample preparation and sample analysis for the HPLC testing was provided by Kaneka directly to Curia. (*Id.* at 118:16-120:4). Dr. Myerson was unaware of substantial aspects of the sample preparation and analysis. (*Id.* at 120:5-123:16).

Also, the sample extraction using microcentrifugation could have resulted in crystallization as the $CoQ_{10}$ became supersaturated or skewed the amount of $CoQ_{10}$ in the samples. (Taylor Decl., Ex. 4 at ¶¶ 14, 16). Additionally, after microcentrifugation, Curia removed and discarded the liquid supernatant, which could have removed any dissolved $CoQ_{10}$ suspended in the supernatant that would have been discarded and ignored in an analysis. (*Id.* at ¶ 15). This could have skewed the amount of $CoQ_{10}$ subject to analysis, including determination of crystal-presence or the ratios of ubiquinol to ubiquinone. (*Id.*).

Dr. Myerson's report fails to even consider that the presence of crystalline or crystalline fragments of reduced $CoQ_{10}$ in the samples extracted using microcentrifugation could be from the extraction method itself. *See Tristrata Tech., inc. v. Mary Kay, Inc.* 423 F. Supp. 2d 456, 464 (D. Del. 2006) ("Whether an expert has accounted for alternative explanations is a factor a court may consider in making the admissibility determination."). Dr. Myerson simply concludes, without any basis, that any assertion that microcentrifugation cause the formation of crystals is incorrect. (Taylor Decl., Ex. 31 at ¶ 15); *see Daubert v. Merrell Dow Phams., Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995) ("[T]he expert's bald assertion of validity is not enough."). Yet, it is Dr. Myerson's burden to support his findings, and, without more, he cannot support his assertion that this extraction method does not favor crystallization. *See MicroStrategy, Inc. v. Business Objects, S.A.*, 429 F. 3d 1344, 1355 (Fed. Cir. 2005) (stating that while an expert need not consider every possible

factor to render a "reliable" opinion, the expert must consider enough factors to make his or her opinion sufficiently reliable in the eyes of the court); *see Kaneka Corp. v. Zhejiang Med. Co., Ltd.*, CV 11-02389, 2017 WL 10591760, at *11 (D. Del. Feb. 22, 2017) (precluding testimony regarding the results of testing as unreliable because Kaneka did not even attempt to show that its experts findings were based on sound science and is independently validated, but instead relied on the expert's *ipse dixit*).

Curia's sample extraction of Coenzymes $Q_9$, $Q_{10}$, and $Q_{11}$ from Defendants' $CoQ_{10}$ soft gel capsules used polar solvents, including extraction using sonication with hexane and methanol and using methananol-isopropanol. (Taylor Decl., Ex. 4 at ¶¶ 17-18). This process of sample preparation method favors the formation of crystalline or crystalline fragments of reduced $CoQ_{10}$ because one of the earliest reports on the preparation of $CoQ_{10}$ taught crystallization from polar solvents such as acetone and ethanol. (Taylor Decl., Ex. 4 at ¶ 17; Ex. 19 at 318-21; Ex. 23 at 19-36; Ex. 24; Ex. 18 at Col. 3, 11. 30-30-65, Col. 4, 1. 64-Col. 5, 1. 44). By using polar solvents to extract Coenzymes $Q_9$, $Q_{10}$, and $Q_{11}$, Curia's sample preparation method could have skewed the presence of crystalline or crystalline fragments of reduced $CoQ_{10}$, making any analysis of the resulting samples unreliable. (Taylor Decl., Ex. 4 at ¶ 18).

The extraction methods used by Curia in preparing the samples for analysis actually favored the formation of crystalline or crystalline fragments of reduced $CoQ_{10}$, making any tests performed on those samples skewed or faulty. Dr. Myerson's dependance on the analysis of the extracted samples to form his opinions necessarily makes his opinions unreliable. Accordingly, Defendants request that the Court exclude any opinions of Dr. Myerson based on his analysis of the flawed samples. *See ZF Meritor LLC v. Eaton Corp.*, 646 F. Supp. 2d 663, 667-68 (D. Del.

2009) (excluding expert opinion that was not "based on reliable data"), aff'd in relevant part, rev'd in part, 696 F.3d 254 (3d Cir. 2012).

**3. Dr. Myerson inconsistently opines in his expert report and expert reply.**

Finally, Dr. Myerson's opinions contained in his expert report and reply report are unreliable because his reports are inconsistent and untimely introduce new theories and analytical protocols. As an initial matter, Dr. Myerson attempts, on several occasions, to change his opinions between his expert report and his reply report. Specifically, Dr. Myerson's statements in paragraphs 43, 44, 45, and 51 of his reply report directly contradict his statements in his expert report. (*See* Taylor Decl., Exs. 6, 31); *see also Recif Resources, LLC v. Juniper Cap. Advisors, L.P.*, No. H-19-2953, 2020 WL 11025602, at *6-7 (S.D. Tx. Oct. 1, 2020) (excluding expert's opinion as unreliable and irrelevant because the opinion was "internally inconsistent").

Dr. Myerson also provides new theories and analytical protocols in his reply report. Specifically, Dr. Myerson provides a new theory or protocol in the following paragraphs: 14 (molecular mobility), 29 (acceptable error of 0.2 degrees two theta), 40 (the only possible crystalline components are ubiquinol and ascorbyl palmitate), 43 ("melting point depression," presence of "other" compounds, "thermal events," "chemical reaction of components," and that he did not rely on DSC results), 44 ("glass transition temperatures"), 49 (first explanation of the "client method"), 50 (wavelength of measurement is of "little consequence"), 51 (no need to quantitatively analyze the components), 53 (discussion of use of $Q_7$ as an internal standard), 57 (description of LOD and LOQ). (*See* Taylor Decl., Exs. 6, 31); *see also Huawei Techs., Co., Ltd. v. Samsung Elec. Co., Ltd.*, 340 F. Supp. 3d 934, 995 (N.D. Cal. 2018) ("The test of whether an expert's opinion constitutes rebuttal or a new opinion...[is] whether a rebuttal attempts to put forward new theories outside the scope of the report it claims to rebut."). Any new analytical theories or protocols asserted in Dr. Myerson's reply report are untimely and improper, given that

he made an about-face with many of the aforementioned analyses. As a result, the Court should exclude any opinions of Dr. Myerson that rely on theories or protocols put forward for the first time in his reply report.

Additionally, Dr. Myerson does not identify which tests he relies upon in forming his opinion in his infringement report. Instead, he merely states a series of conclusions, couched as "his opinion" that the Accused Products infringe the Asserted Claims. (Taylor Decl., Ex. 6 at ¶¶ 77-90). In fact, those conclusions refer generically to the "test results from Curia Global" yet Dr. Myerson did not disclose that he chose not to rely on the majority of the submitted Curia tests results until his deposition—all without a stated rationale. (Taylor Decl., Ex. 29 at 69:20-71:7). Waiting to reveal the analytical framework until the day of deposition, following months of expert report exchange is improper and should results in exclusion of Dr. Myerson's infringement reports.

### C. Dr. Myerson's rebuttal opinion must be excluded because he applies the incorrect legal standard to his analysis.

Defendants move to strike portions of Dr. Myerson's Rebuttal Report as unreliable for two reasons. First, in analyzing claims 1 and 13 of the '044 Patent and claims 5 and 15 of the '080 Patent, Dr. Myerson relied on the incorrect claim construction standard. Specifically, Dr. Myerson improperly applies the "broadest reasonable interpretation" claim construction standard used by the USPTO. (*See* Taylor Decl., Ex. 7 at 20). Second, throughout his rebuttal report, Dr. Myerson improperly relied on the Manual of Patent Examination and Procedure ("MPEP") for legal standards and rationales. (*Id.* at 6, 8, 27-28, 43, 45). Dr. Myerson's reliance on the incorrect legal standard and on the MPEP throughout his rebuttal report necessarily renders his report unreliable and confusing.

As an initial matter, Dr. Myerson's reliance on the "broadest reasonable construction" is improper and contradicts clear Federal Circuit precedent. In the context of patent claims, the

Federal Circuit has instructed courts to construe claim terms according to their plain and customary meaning. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005); *In re CSB-Sys. Int'l, Inc.*, 832 F.3d 1335, 1340 (Fed. Cir. 2016) ("Typically, claims in issued patents are construed using the framework set forth in *Phillips v. AWH Corp.*, which emphasizes considering the plain meaning of the claim terms themselves in light of the intrinsic record."). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention . . . ." *Phillips*, 415 F.3d at 1313.

Unlike actions in federal court, the USPTO applies a "broadest reasonable construction" standard to prosecution proceedings. *See Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 276 (2016). Any claim construction using the USPTO's broader standard is not binding on a court. *See THX, Ltd. v. Apple, Inc.*, No. 13-cv-01161-HSG, 2016 WL 6563340, at *5 (N.D. Cal. Nov. 4, 2016) ("Apple conceded at the claim construction hearing that the Court is not bound by PTAB's construction.").

Here, Dr. Myerson expressly relies on the "broadest reasonable interpretation" standard as the entire claim construction basis in his rebuttal report. (Taylor Decl., Ex. 7 at 20). Specifically, under the "Claim Construction" section of his rebuttal report, Dr. Myerson stated: "I have been informed that the claims musts be construed the same way in determining validity and infringement and that the claims should be given their broadest reasonable interpretation . . . ." (*Id.).* It is clear that Dr. Myerson utilizes this standard to analyze the validity of the '044 Patent and the '080 Patent. Dr. Myerson's reliance on an improper claim construction standard affected his analysis throughout his rebuttal report and, as a result, any opinion of Dr. Myerson based on this incorrect standard is not "the product of reliable principles and methods . . . ." Accordingly, the Court should strike Dr. Myerson's opinions contained in his rebuttal report given that there is

no way to ascertain what opinions rely on the application of "broadest reasonable interpretation" standard in construing claim terms.

Additionally, Dr. Myerson solely relies on the MPEP to support his conclusions on the validity of the '044 Patent and the '080 Patent. (*See* Taylor Decl., Ex. 7 at 43, 45). The MPEP is issued by the USPTO to provide guidance to patent examiners and applicants "on the practices and procedures relative to the prosecution of patent applications before the USPTO." *See* Manual of Patent Examining Procedure, USPTO, (last visited Dec. 12, 2022) https://www.uspto.gov/patents/laws/manual-patent-examining-procedure.guidance. The Federal Circuit has, however, concluded that guidance from the USPTO is neither binding nor authoritative. *See cxLoyalty, Inc. v. Maritz Holdings Inc.*, 986 F.3d 1367, 1375 n.1 (Fed. Cir. 2021) (noting that USPTO guidance "is not, itself, the law of patent eligibility, does not carry the force of law, and is not binding on our patent eligibility analysis"); *see also Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 F. Appx. 1013, 1020 (Fed. Cir. 2019) ("While we greatly respect the PTO's expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance."). Dr. Myerson's reliance on the MPEP as his sole source of legal precedent is improper. Accordingly, to the extent that Dr. Myerson's opinions rely on the legal standards found in the MPEP rather than in Federal Circuit precedent, his opinions should be excluded.

## VI. CONCLUSION

For the foregoing reasons, the Court should grant Summary Judgment in favor of Defendants and exclude the testimony of Plaintiff's experts.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

By: */s/ David E. Moore*
David E. Moore (#3983)
Bindu A. Palapura (#5370)
Brandon R. Harper (#6418)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
dmoore@potteranderson.com
bpalapura@potteranderson.com
bharper@potteranderson.com

*Attorneys for Defendants Designs for Health, Inc. and American River Nutrition LLC*

OF COUNSEL:

Kevin M. Bell
Richard J. Oparil
Scott A.M. Chambers, Ph.D.
Matthew D. Zapadka
Caroline Maxwell
Robert Durkin
ARNALL GOLDEN GREGORY LLP
1775 Pennsylvania Avenue NW, Suite 1000
Washington, DC 20006
Tel: (202) 677-4030

Erin N. Winn
ARNALL GOLDEN GREGORY LLP
171 17th Street NW, Suite 2100
Atlanta, GA 30363
Tel: (404) 873-8500

Dated: December 28, 2022
21084.00001

Public Version Dated: January 27, 2023